510(k) Notification
Electrogastrography (EGG) System NOV 21 2002

510(k) SUMMARY
as required per 807.92(c)

1. Submitters Name, Address:

Medtronic A/S
Tonsbakken 16-18
DK-2740 SKOVLUNDE
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Contact person for this submission: Liselotte Sander
Date submission was prepared: August 20, 2002.

2. Trade Name, Common Name and Classification Name:

A. Trade Name: Electrogastrography (EGG) System

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Polygraf ID	MYE	II	21 CFR 876.1735
Polygram NET	MYE	II	21 CFR 876.1735

3. Predicate Device Identification:

The scientific technology and the functionality and intended use of the Polygram NET and the Polygraf ID are equivalent to 3CPM Company's 3CPM EGG Machine (K 984637)

4. Device Description:

The system is a stationary electrogastrography system for use in the evaluation of gastrointestinal motility disorders. The system measures the myoelectrical activity of the gastrum using sensors situated on the skin. The parameters measured are presented on a computer screen during the capture and are also stored for later display, review, analysis and reporting.

In the daily use, a trained technician, nurse and/or a physician are the main users of the system.

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The main tasks when performing an electrogastrography procedure with a stationary EGG system are:

- Prepare equipment including verification of correct levels for skin/electrode impedance levels.
- Enter patient/study demographic information
- Perform procedure and obtain relevant data
- Review, analysis and post procedure activities
- Create and print a report

The Polygram NET application software runs on the Microsoft Windows® 2000 operating system.

5. Intended Use:

The Polygaf ID with Electrogastrography (EGG) System is intended to record, store view and process gastric myoelectrical activity as an aid in the diagnosis of gastrointestinal motility disorders.

6. Table of Device Similarities and differences to predicate device

Manufacturer	3CPM CO., Inc.	Medtronic Functional Diagnostics
510(k) nummer	**Predicate device** • 3CPM EGG Machine – **K984637**	**New device** **K011468** Polygram NET Electrogastro-graphy (EGG) Application: • Polygraf ID • Polygram NET Electrogastrography Application Software

General:	**Predicate device** 3CPM	**Modified device** Polygram NET Electrogastrography (EGG) Application	**Explanation of the differences compared to the predicate device**
PC. Based	Yes	Yes	same
External data acquisition device	Yes	Yes	same
External amplifier	Yes	No	Better Makes the system simpler
Use of a external Strip Chart Recorder	Yes	No[1]	Better Makes the system simpler.
Measurement setup	On HW devices	By use of protocol	Better

[1] The raw data is presented on the screen formatted as a strip chart. The hole recording or part's of it can be printed or included in the report.

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		settings in SW.	Ensures initially same setting every time
Visualize signals in time domain.	Yes	Yes	same
Running Spectrum Analysis	Yes	Yes	same
Gain	100	1, 10, 100[2]	same
High-Freq.	0.25 Hz	0.25Hz	same
Low Freq.	0.016 Hz	DC, 0.0083Hz; 0.016Hz; 0.030Hz	Better
Offset	0	High Pass filter[3]	Same result
SW high pass filter	NO	Yes	Better. No need for 5 minutes period to "settle down". The recording can begin immediately
Number of channels	1	1 to 4	Better. Gives the ability to analyze the channel with the most significant data
Motion sensor	Yes	Yes	Same
Indications for use	To be used to record electrogastro-grams, as a component of a comprehensive clinical evaluation in patients with symptoms consistent with gastrointestinal motility disorders	Record, store view and analyze gastric myoelectrical activity as an aid in the diagnosis of gastrointestinal motility disorders	Same
Intended populations	Infants, pediatrics to adults	Adults	Less
Sterilization	Accessories are not supplied sterile, manufacturer labels the accessories with cleaning instructions	Electrodes are disposable. Cables are not supplied sterile, manufacturer labels the accessories with cleaning instructions	Same
Biocompatibility	The sensors are the only part that comes into contact with the patients	Same	Same

7. Assessment of non-clinical performance data for equivalence:

Verifications results show that the enhanced system performs as its predicate system.

[2] The Digital resolution is as following: Gain 1 -> 1.12 μV ; Gain 10 -> 0.112 μV; Gain 100 -> 0.0112μV

[3] The Polygraf ID handles signals in the range of f +- 2.5 V. The DC offset is removed by use of a software high pass filter.

8. Assessment of clinical performance data for equivalence:

Clinical trials are not performed. This new system does not raise any new safety or performance issues.

9. Biocompatability:

Not applicable

10. Sterilization:

Not applicable

11. Standards and Guidances:

The Polygraf ID conforms to the following voluntary and mandatory standards:

- EN 60601-1, Medical equipment
- EN 60601-1-1, Electrical Safety
- EN 60601-1-2, Electro magnetic Compatibility
- CAN/CSA 22.2 No. 601.1 – M90

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2002

Mr. Toni Kennet Jørgensen
Regulatory Affairs Specialist
Medtronic Functional Diagnostics A/S
Tonsbakken 16-18
DK-2740 Skovlunde
DENMARK

Re: K014269
Trade/Device Name: Polygraf ID with POLYGRAM NET™ ElectroGastroGraphy (ECG) Application Software
Regulation Number: 21 CFR §876.1735
Regulation Name: Electrogastrography system
Regulatory Class: II
Product Code: 78 MYE
Dated: August 20, 2002
Received: August 23, 2002

Dear Mr. Jørgensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K014269

Device Name: ElectroGastroGraphy (EGG) Application Software

Indications For Use:

The PolygrafID with POLYGRAM NET™ ElectroGastroGraphy Application is intended to record, store, process and view gastric myoelectrical activity as an aid in the diagnosis of gastrointestinal motility disorders.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Lagzdins

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014269

(Optional Format 3-10-98)

Prescription Use ✓